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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,641	09/19/2000	Y. Tom Tang	788CIP2C	4944

7590 06/19/2002
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EXAMINER

ARTHUR, LISA BENNETT

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/19/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/664,641

Applicant(s)

TANG ET AL.

Examiner

Lisa B. Arthur

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 10,11,19-21 and 27 is/are pending in the application.
- 4a) Of the above claim(s) 19,21 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 10,11 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 10,11,19-21 and 27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☒ Other: sequence alignment.

1. This action is in response to the papers filed April 2, 2002. Currently, claims 10, 11, 19-21 and 27 are pending but claims 19, 21 and 27 have been withdrawn from consideration by the restriction requirement made in the office action mailed December 19, 2001.

Applicant's election of Group 45, claims 10, 11 and 20 drawn to polypeptides encoded by SEQ ID NO 10 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 10, 11 and 20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 10, 11 and 20 are drawn to a polypeptide encoded by SEQ ID NO 10, 99% identical to SEQ ID NO 20 or to a composition containing a polypeptide encoded by SEQ ID NO 10. The specification teaches that the nucleic acids of SEQ ID Nos 1-35 are expressed sequence tags (ESTs) identified by sequencing by hybridization. These polynucleotide sequences were analyzed for open reading frames and the sequences were compared to sequence databases to determine sequence homologies to known genes and encoded polypeptides (Table 2). According to Table 2, the nucleic acid sequence of SEQ ID NO 10 exhibits 97% similarity to homo sapien CAGF28. The bulk of the specification is directed to general utilities for the encoded polypeptides as for the

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generation of antibodies, molecular weight markers and as food supplements, as diagnostics and therapeutics in disorders involving aberrant protein expression or biological activity, and for drug screening (see pages 5-6). The specification provides general methodologies for isolation and recombinant expression of the polypeptide (page 28-33). The specification discusses uses for polypeptides that have cytokine and cell proliferation/differentiation activity (pages 41-43), stem cell growth factor activity (pages 43-45), hematopoiesis regulating activity (pages 45-47), tissue growth activity (pages 47-49) immune stimulating or suppressing activity (page 49-55), activin/inhibin activity (page 55), chemotactic/chemokinetic activity (page 56), hemostatic and thrombolytic activity (page 57) cancer diagnosis and therapy (pages 57-59) receptor ligand activity (pages 59-61), antiinflammatory activity (pages 63-64) and associations with leukemias and nervous system disorders (page 64-67). However, the specification does not teach that a polypeptide encoded by SEQ ID NO 10 has any of these or any other specific activity. SEQ ID NO 10 is only identified in the specification as having 97% sequence identity to a nucleic acid called CAGF28. No particular activity has been associated with CAGF28 such that a determination of the function of the polypeptide of SEQ ID NO 10 can be determined from the specification. The utilities given in the specification are general utilities for which any protein could be used and consequently do not constitute a specific and substantial utility. Lechner et al. (Nucleic Acids Research (2000) 28(14) 2741-2751) appear to have isolated a protein having the same amino acid sequence as that encoded by SEQ ID NO 10 (see Figure 3). Lechner et al. have identified this polypeptide, which they call PTIP, as a one which binds to the

activation domain of a transcription factor called Pax2 and other Pax proteins. Lechner et al. Also found that PTIP binding can be inhibited by the octapeptide transcription repression domain of the Pax proteins and teach that PTIP and Pax2 co-localize in the cell nucleus to actively expressed chromatin and nuclear matrix fraction. None of this information about the activity of the polypeptide encoded by SEQ ID NO 10 is taught in the specification to establish a specific and substantial use of this polypeptide as is required under the statute. Every application is required to assert the intended use of an invention. So consequently, since this specification only provides general utilities for any protein and possible utilities which some of the disclosed polypeptides may possess and does not provide an asserted specific and substantial utility for the polypeptide of SEQ ID NO 10, this invention lacks patentable utility.

4. Claims 10, 11 and 20 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 10, 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Margolis et al. (HUMAN GENETICS (1997) 100: 114-122).

Margolis et al. And expressed sequence encoding a polypeptide with is 99.9% similar to that of SEQ ID NO 10 (see the attached sequence alignment). The attached alignment identifies the sequence of Margolis as CAFG28 which is the same nomenclature used in Table 2 of the specification for SEQ ID NO 10. Margolis et al. does not teach the isolated polypeptide encoded by the polynucleotide sequence. However, Margolis et al. does teach that the polynucleotides which they isolated do encoded polypeptides and suggest that these polypeptides may function as transcription factors. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made expressed the polypeptides encoded by the polynucleotides isolated by Margolis et al. to make the invention as a whole because Margolis et al. suggests that the isolated proteins would be useful as transcription factors.

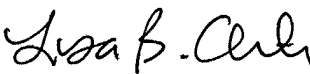
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7. No claims are allowable over the prior art.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa B. Arthur whose telephone number is (703) 308-3988. The examiner can normally be reached on Monday and Tuesday from 7:00 am to 3:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800 1600

June 17, 2002